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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/561,040	10/16/2006	Atsushi Miyawaki	P28994	3808
7055 7590 03/03/2009 GREENBLUM & BERNSTEIN, P.L.C. 1950 ROLAND CLARKE PLACE RESTON, VA 20191				
EXAMINER KAM, CHIH MIN				
ART UNIT		PAPER NUMBER		
1656				
NOTIFICATION DATE		DELIVERY MODE		
03/03/2009		ELECTRONIC		

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

gbpatent@gbpatent.com  
pto@gbpatent.com

# Office Action Summary

Application No.

10/561,040

Applicant(s)

MIYAWAKI ET AL.

Examiner

CHIH-MIN KAM

Art Unit

1656

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 31 December 2008.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-22 is/are pending in the application.
- 4a) Of the above claim(s) 1-7 and 14-22 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 8-13 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 16 October 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date 10/17/08; 2/07/19/08
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☒ Other: FI prot. (sequence match)

## DETAILED ACTION

### *Election/Restrictions*

1. Applicant's election with traverse of Group II, claims 8-13 and SEQ ID NO:19 as the elected nucleotide sequence, in the response to restriction requirement filed December 31, 2008 is acknowledged. The traversal is on the ground(s) that the Office has not provided any rationale as to why the groups of inventions are not so linked to form a single general inventive concept, nor has indicated what it alleges the special technical feature of the groups of invention to be. Further, the search and examination of all the claims would not place a serious burden on the Examiner, especially regarding the sequence of SEQ ID NO:13, 15, 17, 19 and 21, which each of nucleotides encodes a fluorescent protein and the sequence homology among SEQ ID NOs:13, 15, 17, 19 and 21 is very high (i.e., >98%). Applicants' response has been fully considered. Regarding Groups I and II, the arguments are not persuasive because the special technical feature of Group I is the fluorescent protein with specific physical properties and/or with specific amino acid sequence, while the special technical feature of Group II is the nucleotide sequence that encodes a fluorescent protein with specific peptide sequence or the variant thereof. Furthermore, the search and examination on all the variants of the fluorescent proteins would pose serious burden on the Examiner. Moreover, there is art (Almond *et al.*, US 2003/0157643; see below) reads on all the claims of Group II, thus, the special technical feature is known and the claimed subject matter does not define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art. Regarding the nucleotide sequences of SEQ ID NOs:13, 15, 17, 19 and 21, the arguments are found persuasive, thus, all the nucleotide sequences in claims 8-13 will be included for examination.

The requirement is still deemed proper and is therefore made FINAL. Therefore, claims 8-13 and nucleotide sequences of SEQ ID NOs:2, 13, 15, 17, 19 and 21 are examined.

*Informalities*

The disclosure is objected to because of the following informalities:

2. The specification does not cite the continuation data for the instant application.

Appropriate correction is required.

3. Fig. 3 recites amino acid sequences of fluorescent protein, however, these sequences were not identified with "SEQ ID NO:" in the brief description of the drawings at page 9. If these sequences were not included in the Sequence Listing, Applicant must comply with the requirements of sequence rules (37 CFR 1.821-1.825) to include all the sequences in the sequence listing. Appropriate correction is required.

*Claim Rejections - 35 USC § 101*

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

4. Claims 8-13 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. The claim is directed to a DNA, a vector or a transformant. As written, the claim does not explicitly indicate the hand of man. Insertion of "isolated" in connection with the DNA or transformant is suggested. See MPEP § 2105.

See also *American Wood v. Fiber Disintegrating Co.*, 90 U. S. 566 (1974); *American Fruit Growers v. Brogdex Co.*, 283 U. S. 1 (1931); *Funk Brothers Seed Co. v. Kalo Inoculant*, 33 U. S. 127 (1948); and *Diamond v. Chakrabarty*, 206 USPQ 193 (1980).

*Claim Rejections - 35 USC § 112*

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 8-13 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
6. Claims 8, 12 and 13 are indefinite because of the use of the term “the protein of the present invention”. The term cited renders the claim indefinite, it is not clear what protein the term refers to since there is no characteristics of the protein indicated. Claims 12-13 are included in this rejection for being dependent on a rejected claim and not correcting the deficiency of the claim from which they depend.
7. Claims 9-11 are indefinite because of the use of the term “several amino acids” or “several nucleotides”. The term cited renders the claim indefinite, it is not clear how many amino acids or nucleotide the term “several” refers to.

*Claim Rejections - 35 USC § 102*

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002

do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

8. Claims 8-13 are rejected under 35 U.S.C. 102(e) as anticipated by Almond *et al.* (U.S. Pub. No. 2003/0157643 A1, filed December 9, 2002).

Almond *et al.* teaches a synthetic nucleic acid molecule comprising a nucleotide sequence that encodes a fluorescent protein, e.g., the DNA sequence of SEQ ID NO:21 encoding a humanized green fluorescent protein (Figs 2A-2B; paragraphs [0029]; claim 8), a vector comprising the DNA (paragraphs [0017], [0064]; claim 12), and a host cell comprising the vector (paragraph [0020]; claim 13). The nucleotide sequence of SEQ ID NO:21 has 86.3% sequence identity to the DNA encoding SEQ ID NO:1 (See attached sequence match). The nucleotide sequence of SEQ ID NO:21 also has sequence identity of 81.3%, 80.8%, 79.9%, 79.9%, 81.3% and 80.4%, respectively, to the nucleotide sequence of SEQ ID NO:13, 15, 17, 19, 2 and 21, respectively (See attached sequence match). Since the claim does not specifically define the term "several", the nucleotide sequence of SEQ ID NO:21 reads on the part (b) of claims 9-11.

### *Conclusion*

9. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chih-Min Kam whose telephone number is (571) 272-0948. The examiner can normally be reached on 8.00-4:30, Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon Weber can be reached at 571-272-0925. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Chih-Min Kam/

Primary Examiner, Art Unit 1656

CMK

February 25, 2009